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Jay A. Dittman

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BRINKS HOFER GILSON & LIONE/INDY/COOK

BRINKS HOFER GILSON & LIONE

CAPITAL CENTER, SUITE 1100

201 NORTH ILLINOIS STREET

INDIANAPOLIS, IN 46204-4220

EXAMINER

KOHARSKI, CHRISTOPHER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Acknowledgements

The Examiner acknowledges the reply filed 05/06/2009 in which claims 1 and 4 were amended and new claim 29 was added. Currently claims 1, 2, 4-6 and 8-29 are pending for examination in this application with claims 22-28 withdrawn from a previous election restriction. Additionally, the Examiner also acknowledges the amended specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-5 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 4-5, amended independent claim 1, now references a “uniform inner diameter”, however the dependant claims still reference a “uniform diameter” not specific to which diameter is being referenced.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4-6, 8-15, and 20-21 are rejected under 35 U.S.C 103(a) as being unpatentable over Parker (USPN5,700,253) in view of Lepulu et al. (USPN6,533,770) in further view of Parker (USPN5,769,830).

Regarding claims 1-2, 4-6, 8-15, and 20-21, Parker et al. discloses an introducer sheath (Figure 3), comprising: an PTFE inner tube (46) having a passageway extending longitudinally therethrough, said passageway having a substantially uniform diameter; a coil (48) made of flat ribbon having a plurality of coil turns extending longitudinally around said inner tube (46), and a plurality of predetermined spacing's between said turns; and a nylon outer tube (44) positioned longitudinally around said coil (48) and said inner tube (46) connected to inner tube through the spacing's between said turns, wherein said spacing's between said coil turns have a uniform width; a radiographic marker tube (72) comprises a polyamide (see abs) and is disposed along said sheath between said inner tube (46) and said outer tube (44) (Figures 1-5).

Parker meets the claim limitations as described above except for the introducer sheath diameter and side hole.

However, Lepulu et al. teaches a cannula and method of manufacture.

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Regarding claims 1-2, 4-6, 8-15, and 20-21, Lepulu et al. teaches discloses an introducer sheath (Figure 22), comprising: a tube (372) having a passageway extending longitudinally therethrough ranging from an inner diameter of 16-29 French (col 18, ln 50-60), said passageway having a substantially uniform diameter; a side port (390) located in the sheath wall (Figure 22).

At the time of the invention, it would have been obvious to construct the device of Parker to the size as taught by Lepulu et al. because it is well known in the medical arts to adjust the size medical devices to different patients and procedures. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Lepulu et al. (cols 1-2). Additionally, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See, *In re Aller*, 105 USPQ 233 (CCPA 1955).

The modified Parker meets the claim limitations as described above except for the claimed Shore D hardness and radioopaque densities.

However, Parker teaches a guiding catheter.

Regarding claims 1-2, 4-6, 8-15, and 20-21, Parker teaches discloses an introducer sheath (Figures 1-2), comprising: a tube (10) with a varied Shore D hardness from 50-65 (col 4, ln 1-20, 40-50) having a passageway extending longitudinally therethrough, said passageway having a substantially uniform diameter; a coil (26)

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located in the sheath wall, a radioopaque marker (27, 34) with varied weight percents from 10-90% filler (col 4, ln 60-67, col 5, ln 1-40).

At the time of the invention, it would have been obvious to construct the invention of the modified Parker with the properties as disclosed by Parker ('830) because it is well known in the art to vary the radioopaque properties to enhance visibility within the body and to vary the material hardness to optimize insertion and tracking within the body. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Parker (cols 1-2). Additionally, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See, *In re Aller*, 105 USPQ 233 (CCPA 1955).

Claim Rejections - 35 USC § 103

Claims 16-19 and 29 are rejected under 35 U.S.C 103(a) as being unpatentable over Parker (USPN5,700,253) in view of Lepulu et al. (USPN6,533,770).

Regarding claims 16-19 and 29, the modified Parker discloses the claimed invention except for specific wire coil sizes and spacing and specific tubular materials. Lacking specific criticality, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the modified device of Parker with the metal coil measurements as claimed because it is well known in the art to vary the coil size, spacing, and length in order to adjust the stiffness of the sheath in order to promote insertion without kinking and enhance tracking within the patient, since it has

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been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See *In re Aller*, 105 USPQ 233 (CCPA 1955). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the modified Parker tubes of the same material since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Response to Arguments

Applicant's arguments filed 05/06/2009 have been fully considered but they are not persuasive. Applicant's Representative asserts that the prior art combination of Parker (USPN5,700,253) in view of Lepulu et al. (USPN6,533,770) in further view of Parker (USPN5,769,830) does not disclose the introducer sheath with the specific inner diameter and Shore D hardness.

The Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

The Examiner asserts that the prior art of records meets the claim limitations. The device of Parker ('253) discloses a structurally similar device as currently claimed by Applicant, while Lepulu et al. teaches a catheter with the internal diameter as claimed and Parker ('770) teaches a catheter tube with the Shore D hardness as claimed. Lacking specific criticality for the disclosed material measurements and

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hardness, the Examiner asserts that it is well known in the medical arts to adjust the size, shape, and materials of medical tubes whether it be for insertion or fluid movement, to properly adjust for the size of the patient and for the type of medical procedure being performed.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 8/17/2009

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763